

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

JAMES REID, individually and on behalf of all others similarly situated, Plaintiff	: : : : :	CIV. NO. 09-5262
v.	:	
HEMISPHERX BIOPHARMA, INC., AND WILLIAM A. CARTER, Defendants	: : :	

PAUL MCGOVERN, individually and on behalf of all others similarly situated, Plaintiff	: : : : :	CIV. NO. 09-5682
v.	:	
HEMISPHERX BIOPHARMA, INC., AND WILLIAM A. CARTER, Defendants	: : :	

CATHERINE A. KLETMAN, individually and on behalf of all others similarly situated, Plaintiff	: : : : :	CIV. NO. 09-5870
v.	:	
HEMISPHERX BIOPHARMA, INC., AND WILLIAM A. CARTER, Defendants	: : :	

STUART SCHUPLER and SHIJING LIN, on behalf of themselves and all others similarly situated, Plaintiff	: : : : :	CIV. NO. 09-5931
v.	:	
HEMISPHERX BIOPHARMA, INC., AND WILLIAM A. CARTER, Defendants	: : :	

GEORGE M. DAFORNO, individually and on behalf of all others similarly situated, Plaintiff	: : : : :	CIV. NO. 09-6173
v.	:	

HEMISPHERX BIOPHARMA, INC., AND
WILLIAM A. CARTER,
Defendants

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MICHAEL K. HANNA, derivatively on behalf
of Hemispherx Biopharma, Inc.,
Plaintiff

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v.

CIV. NO. 09-6160

:

WILLIAM A. CARTER, et al.
Defendants

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ROBERT RANK, derivatively on behalf of
Hemispherx Biopharma, Inc.,
Plaintiff

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v.

CIV. NO. 10-262

:

WILLIAM A. CARTER et al.,
Defendants

:
:

GARY BONET, derivatively on behalf of
Hemispherx Biopharma, Inc.,
Plaintiff

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:
:

v.

CIV. NO. 10-326

:

WILLIAM A. CARTER,
Defendants

:
:

ORDER

Plaintiff shareholders have filed five securities fraud class action lawsuits against Hemispherx Biopharma, Inc., Chief Executive Officer and Board Chairman William A. Carter, and Medical Director David R. Strayer. Plaintiffs – who purchased Hemispherx common stock between February 18, 2009 and December 1, 2009 – allege that Defendants violated the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995. See 15 U.S.C. § 78j; 17 C.F.R. § 240.10b-5. Shareholders have also filed three derivative lawsuits on behalf of the Company against Mr. Carter and other Board members, alleging state law claims for breach of

fiduciary duty, unjust enrichment, and waste of corporate assets. All eight actions are based on the same allegations: that Hemispherx knowingly issued materially false and misleading statements that artificially inflated the Company's stock price, thus harming both stockholders – who relied on the fraudulent financial statements – and the Company itself.

On February 12, 2010, I consolidated the eight cases, named the Hemispherx Investor Group as Lead Plaintiffs, and approved their selection of the law firms of Berger Montague and Brower Piven as Lead Counsel. (Doc. No. 26.) On March 1, 2010, the Hemispherx Investor Group submitted a Consolidated Class Action Complaint. (Doc. No. 28.) On March 12, 2010, Defendants filed a Motion to Dismiss the Consolidated Complaint. (Doc. No. 29.) On March 26, 2010, Lead Plaintiffs submitted their Response, and on April 6, 2010, Defendants filed a Reply. See Doc. Nos. 32, 36.

AND NOW, this 19th day of April, 2010, upon consideration of Defendants' Motion to Dismiss (Doc. No. 29) and all related filings, it is hereby **ORDERED** that Defendants' Motion is **DENIED** as follows:

1. Hemispherx is a Philadelphia-based pharmaceutical Company that developed Ampligen, an experimental drug for the treatment of chronic fatigue syndrome. Plaintiffs allege that because, during the Class Period, Hemispherx was in desperate financial straits, the Company sought to raise money through offerings of securities at a price that had been artificially inflated through the Company's knowing issuance of materially false statements concerning Ampligen. Defendants believe that because there is no medical treatment for CFS – a disease suffered by millions of people – Ampligen, once approved by the U.S. Food and Drug Administration for treatment of CFS, would bring enormous profits to the Company.

As alleged, on July 7, 2008, the FDA received the Company's New Drug Application for Ampligen. (Doc. No. 28 at ¶ 38.) In a February 2009 press release, the Company made the knowingly false announcement that the FDA had delayed its decision on the Ampligen application until May 25, 2009. (Id. at ¶¶ 9, 47-48.) In a March 2009 conference call with investors and analysts, CEO Carter made the knowingly false statement that the FDA was not awaiting any data or documents from the Company that might delay Ampligen's approval. (Id. at ¶ 9, 52-59.) In early May 2009, the Company announced its plan to issue more than \$30 million in stock. (Id. at ¶¶ 40-46, 60-63.) On May 26, 2009, the Company issued a press release stating that the FDA had advised the Company it could take two additional weeks to review the Ampligen application, and adding falsely that "the FDA did not request additional information from the Company at this time." (Id. at ¶ 65.) The Company's stock reached a high of \$3.75 a share on June 4th.

2. Plaintiffs allege that on September 19, 2009, TheStreet.com reported that Carter had acknowledged that the FDA would not act on the Ampligen application until the Company addressed manufacturing deficiencies the Agency had identified. Similar news reports followed. (Doc. No. 28 at ¶ 70.) On November 2, 2009, a Company press release confirmed that Hemispherx had "outstanding queries from the FDA" regarding its Ampligen application, and planned to complete its submissions to the Agency over the next two months. (Id. at ¶¶ 11, 73.) With this disclosure, the price of Hemispherx stock dropped more than 20 percent from \$1.45 a share on Nov. 2nd to \$1.13 a share at the close of business on November 3rd. (Id. at ¶¶ 12, 74.) After the Company announced on December 1, 2009 that the FDA had rejected its Ampligen application, the price fell more than 40 percent, to \$0.71 a share. (Id. at ¶¶ 13-14, 78.) Plaintiffs also allege that they relied to their detriment on all Defendants' knowingly false statements. (Id. at ¶¶ 134, 145.)

3. In their Motion to Dismiss, Defendants argue that the Consolidated Complaint fails to meet the PSLRA's heightened pleading standard because Plaintiffs do not: (1) plead with particularity an actionable misstatement or omission of material fact or (2) allege a strong inference of *scienter* – an intention to deceive, manipulate, or defraud. (Doc. No. 29 at 48-52, 69-78.) Defendants further argue that their public statements regarding Ampligen are immune from liability because they are: (1) statements of belief or opinion, or (2) “forward-looking” statements accompanied by meaningful cautionary language that qualify for protection under the “safe harbor” provision of the PSLRA. Thus, Defendants allege, the Consolidated Complaint should be dismissed in its entirety. (Id. at 52-66.)

4. Plaintiffs respond that Defendants' statements as alleged are actionable because: (1) they were knowingly false, and (2) the statements were neither forward-looking nor accompanied by meaningful cautionary language and thus do not qualify for safe harbor protection. (Doc. No. 32 at 44-52.) Plaintiffs also argue that to the extent Defendants dispute these allegations, they impermissibly rely on evidence well outside the Consolidated Complaint. (Id. at 23.)

Defendants' arguments are simply incorrect. Plaintiffs have alleged that Defendants made specific false statements about the Ampligen/FDA approval process, knowing the statements were false, to encourage investors to purchase Hemispherx stock at an artificially high price, and that Plaintiffs relied on Defendants' statements to their detriment. These classic allegations of fraud certainly can survive a Rule 12 dismissal motion.

5. To bring a class action pursuant to Section 10(b) of the Exchange Act and Rule 10-b, Plaintiffs must allege that Defendants: “(1) made a misstatement or omission of material fact (2) with *scienter* (3) in connection with the purchase or the sale of a security (4) upon which the plaintiffs

reasonably relied and (5) the plaintiffs' reliance was the proximate cause of their injury." GSC Partners CDO Fund v. Washington, 368 F.3d 228, 236 (3d Cir. 2004).

Under the PSLRA's heightened pleading standard, Plaintiffs must also: (1) "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity" and (2) "state with particularity facts giving rise to a strong inference that [Defendants] acted with the required state of mind." Institutional Investors Group v. Avaya, Inc., 564 F.3d 242, 252-53 (3d Cir. 2009). In determining whether Plaintiffs have met these requirements, I must accept all factual allegations in the Consolidated Complaint as true. Id. at 252; Fed. R. Civ. P. 12(b)(6).

6. Plaintiffs explicitly and methodically set out the allegedly fraudulent statements, when, where, and by whom the statements were made. See Doc. No. 28 at ¶¶ 47-76; In re Advanta Sec. Litig., 180 F.3d 525, 534 (3d Cir. 1999) (heightened pleading standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story"). In addition, Plaintiffs describe the reasons each statement was false and material, and how they relied on those statements to their detriment. (Doc. No. 28 at ¶¶ 47-76.)

7. As I have described, the challenged statements relate to: (1) Defendants' explanation of why the FDA delayed deciding the New Drug Application for Ampligen – which the Company attributed to FDA staffing problems; and (2) Defendants' assurances regarding the safety and efficacy of the medication. By thus identifying each misleading statement with particularity, Plaintiffs have satisfied the first prong of the heightened pleading requirement. See, e.g., In re RAIT Fin. Trust Litig., No. 07-3148, 2008 U.S. Dist. LEXIS 103549, at *54 (E.D. Pa. Dec. 22, 2008).

8. Plaintiffs must also plead with particularity facts making out *scienter* – a "strong

inference” of “reckless or conscious behavior.” Avaya, 564 F.3d at 267. See also Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007) (“[T]he inference of scienter must be more than merely ‘reasonable’ or ‘permissible’—it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.”). Plaintiffs must thus allege that the corporate officers named in the Complaint – Carter and Strayer – had “ample reason to know of the falsity of their statements.” In re Stonepath Group, Inc. Sec. Litig., 2006 U.S. Dist. LEXIS 15808, at *36 (E.D. Pa. Apr. 3, 2006). In determining whether Plaintiffs have made out *scienter*, I need not “scrutinize each allegation in isolation but to [instead must] assess all the allegations holistically.” Avaya, 564 F.3d at 267.

9. Plaintiffs allege that because Carter and Strayer were desperate for investment monies, they intentionally or recklessly misled the public about the Ampligen Application both to attract new investors and artificially to inflate the Company’s stock price before several securities offerings. See Doc. No. 28 at ¶¶ 20-24; 41-43, 88-93, 106-115. Hemispherx is a small company that made only one drug besides Ampligen for commercial distribution. As the Company’s highest ranking officers, Carter and Strayer allegedly have comprehensive knowledge of all its operations and special knowledge concerning Ampligen, which Carter invented. See Doc. No. 29 at 1; Doc. No. 32 at 56-58.

In these circumstances, Plaintiffs have certainly alleged facts sufficient to make out an inference of *scienter*. See, e.g., Avaya, 564 F.3d at 270 (“Given the specificity and repetition of the analysts’ questions, McGuire’s position as Chief Financial Officer, and the alleged state of Avaya’s business at the time the questions were asked, there is a strong inference that McGuire’s

behavior reached this threshold of recklessness”); In re RAIT Fin. Trust Sec. Litig., U.S. Dist LEXIS 103549, at *50 (“Because the alleged misstatements involved RAIT’s core business operations and because the Officer Defendants had ample reason to know of the falsity of their statements, there is a strong inference of scienter in this case.”).

10. Defendants argue that some of the statements Plaintiffs challenge are non-actionable expressions of belief or opinion. (Doc. No. 29 at 52-57.) The Supreme Court has held, however, that in securities cases such expressions may be actionable because statements of “judgment can be uttered with knowledge of truth or falsity just like more definite statements.” Virginia Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1095-96 (1991); see also In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357, 372 n.14 (3d Cir. 1993) (although Virginia Bankshares concerned a claim under § 14(a) of the Exchange Act, its reasoning also applies to cases brought under § 10(b)). Thus, a plaintiff asserting a claim under § 10(b) and Rule 10b-5 based on an allegedly false statement of belief or opinion “must allege with particularity that defendants did not sincerely believe the opinion they purported to hold.” Podany v. Robertson Stephens, Inc., 318 F. Supp. 2d 146, 154 (S.D.N.Y. 2004). This is what Plaintiffs have done here.

11. Defendants correctly identified that a number of the challenged statements were conditioned by the phrases “we believe,” “we feel,” “we think that,” and the like. (Doc. No. 29 at 54-55.) Because Plaintiffs allege that these statements were objectively false, they are actionable. (Doc. No. 32 at 45.) Moreover, Plaintiffs have alleged that Defendants knew all the challenged statements concerning the reasons for the FDA’s delay and Ampligen safety and efficacy studies – even those with conditional language – were false at the time they made them to investors. See Doc. No. 28 at ¶¶ 20-24; 40-49, 55-58, 88-93, 106-115. In these circumstances, the challenged statements

are not protected statements of opinion.

12. Nor are the challenged statements protected because they are “forward-looking.” The PSLRA’s “safe harbor” may “immuniz[e] from liability any forward-looking statement, provided that: the statement is identified as such and accompanied by meaningful cautionary language, or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood.” Avaya, 564 F.3d at 254. The statute defines “forward-looking statement” to include “a statement or the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer,” as well as “any statement of assumptions underlying or relating to any [such] statement.” 15 U.S.C. § 78u-5(i)(1)(B), (D). Forward-looking statements will be protected under the safe harbor only if they are identified as forward-looking and “accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.” Id. at § 78u-5(c)(1)(A)(I).

Statements of existing facts or circumstances – or omissions of existing facts or circumstances – are not forward-looking and do not qualify for safe harbor protection. Avaya, 564 F.3d at 255; In re Cell Pathways, Inc. Sec. Litig., No. 99-752, 2000 U.S. Dist. LEXIS 8584, at *42 (E.D. Pa. June 21, 2000) (“[A]llegations based upon omissions of existing facts or circumstances do not constitute forward looking statements.”).

13. Defendants argue that their statements regarding the timeframe for the FDA’s decision on the Ampligen NDA were forward-looking because they are “plans or objectives relating to the[ir] products.” (Doc. No. 29 at 60.) Plaintiffs allege that in making these statements, however, Defendants knowingly omitted important facts regarding the Agency’s serious concerns respecting

the Ampligen application – concerns that would cause significant delay, at the very least. (Doc. No. 32 at 47-49.) Indeed, this is the gravamen of the Consolidated Complaint: that Defendants intentionally misled investors about the FDA’s decision timetable by omitting the actual reasons for the delay – that the Agency had asked the Company for additional documents relating to Ampligen’s safety and effectiveness. See Doc. No. 28 at ¶¶ 20-24; 41-43, 88-93, 106-115.

Taking these allegations as true, as I must at this early stage, Defendants’ statements were not “forward-looking,” regardless of the “meaningful cautionary language” employed. See., e.g., Marsden v. Select Med. Corp., No. 04-4020, 2006 U.S. Dist. LEXIS 16795, at *24-25 (E.D. Pa. Apr. 6, 2006) (statements may not be classified as forward-looking because plaintiffs allege that Defendants “withheld present information”); accord In re MobileMedia Sec. Litig., 28 F. Supp. 2d 901, 930 (D.N.J. 1998). Accordingly, the safe harbor does not apply.

14. In sum, the Consolidated Complaint satisfies the heightened pleading requirements applicable here. In their 82 page Memorandum of Law, Defendants rely on innumerable facts well outside the Consolidated Complaint to argue that Plaintiffs’ claims are not cognizable. To state Defendants’ argument is to refute it. If, at the conclusion of discovery, Defendants believe the record supports judgment in their favor as a matter of law, they may seek summary judgment. Their attempt to “pre-try” the case, however, is not appropriate. Accordingly, I will deny Defendants’ Motion to Dismiss (Doc. No. 29).

AND IT IS SO ORDERED.

/s/ Paul S. Diamond

Paul S. Diamond, J.

